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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,369	05/24/2007	Peter R. Brink	13533/48203	3149

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KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER

GIBBS, TERRA C

ART UNIT	PAPER NUMBER
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1635

MAIL DATE	DELIVERY MODE
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07/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/583,369		BRINK ET AL.	
	Examiner		Art Unit	
	TERRA C. GIBBS		1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-23 are pending in the instant application.

Claims 1-23 are subject to restriction as detailed below:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claim 14, drawn to a method of delivering an oligonucleotide or a plasmid expressing an oligonucleotide into a target cell comprising introducing the oligonucleotide into a target cell and contacting the target cell with the donor cell under conditions permitting the donor cell to form a gap junction channel, wherein the gap junction channel is composed of connexin 43, classifiable in class 514, subclass 44, for example.

Group II. Claim 15, drawn to a method of delivering an oligonucleotide or a plasmid expressing an oligonucleotide into a target cell comprising introducing the oligonucleotide into a target cell and contacting the target cell with the donor cell under conditions permitting the donor cell to form a gap junction channel, wherein the gap junction channel is composed of connexin 40, classifiable in class 514, subclass 44, for example.

Group III. Claim 16, drawn to a method of delivering an oligonucleotide or a plasmid expressing an oligonucleotide into a target cell comprising introducing the oligonucleotide into a target cell and contacting the target cell with the donor cell under conditions permitting the donor cell to form a gap junction channel, wherein the gap

Art Unit: 1635

junction channel is composed of connexin 45, classifiable in class 514, subclass 44, for example.

Group IV. Claim 17, drawn to a method of delivering an oligonucleotide or a plasmid expressing an oligonucleotide into a target cell comprising introducing the oligonucleotide into a target cell and contacting the target cell with the donor cell under conditions permitting the donor cell to form a gap junction channel, wherein the gap junction channel is composed of connexin 32, classifiable in class 514, subclass 44, for example.

Group V. Claim 18, drawn to a method of delivering an oligonucleotide or a plasmid expressing an oligonucleotide into a target cell comprising introducing the oligonucleotide into a target cell and contacting the target cell with the donor cell under conditions permitting the donor cell to form a gap junction channel, wherein the gap junction channel is composed of connexin 37, classifiable in class 514, subclass 44, for example.

Claim 19 links the invention of Groups I-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 19. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional

Art Unit: 1635

application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 1-13 and 20-23 links the invention of Groups I-V.0. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1-13 and 20-23. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other, because of the following reasons:

Groups I-V are directed to related inventions in that they each are directed to a method of delivering an oligonucleotide or a plasmid expressing an oligonucleotide into

Art Unit: 1635

a target cell comprising introducing the oligonucleotide into a target cell and contacting the target cell with the donor cell under conditions permitting the donor cell to form a gap junction channel. However, the related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions of Groups I-V are patentably distinct from each other since they are directed to methods of delivering an oligonucleotide or a plasmid expressing an oligonucleotide into a target cell under conditions permitting the formation of uniquely different gap junction channels, namely connexin 43, connexin 40, connexin 45, connexin 32, and connexin 37, respectively. The uniquely different gap junction channels formed by Groups I-V are known in the art to possess materially different design (e.g. nucleic acid sequence). Therefore, a search of the method of Group I would not necessarily reveal art against the methods of Groups II-V, and vice versa. Similarly, a search of the method of Group II would not necessarily reveal art against the methods of Group III-V, and vice versa. Additionally, a search of the method of Group III would not necessarily reveal art against the methods of Group IV and V, and vice versa. Lastly, a search of the method of Group IV would not necessarily reveal art against the method of Group V, and vice versa. Because these Groups form nucleic acid sequences which are each of a materially different design, the inventions are therefore not obvious variants. Since it is an undue burden to search and examine these multiple inventions in a single application, due to

Art Unit: 1635

the fact that the searches are divergent and non-coextensive, and require different search queries for examination purposes, restriction is proper therefore. Furthermore, restriction for examination purposes as indicated is proper because the prior art applicable to one invention would not likely be applicable to the other invention because the different inventions require the use of different search queries for examination purposes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Also, because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions require a different field of search (see MPEP 808.02), restriction for examination purposes as indicated is proper.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must

Art Unit: 1635

include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1635

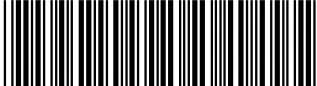
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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

June 30, 2008

/Terra Cotta Gibbs/

Application Number 	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/583,369	BRINK ET AL.	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	